

Phillip Wm. Lear  
Lear & Lear PLLC  
808 E South Temple Street  
Salt Lake City, UT 84102  
Telephone: (801) 538-5000  
Facsimile: (801) 538-5001  
Email: [phillip.lear@learlaw.com](mailto:phillip.lear@learlaw.com)  
Local Attorney for Linda P. Smith

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH  
CENTRAL DIVISION

LINDA P. SMITH,

Case No. 1:21-cv-00047-CMR

*Plaintiff*

v.

XAVIER BECERRA, in his capacity  
as the Secretary of the United States  
Department of Health and Human  
Services,

JURY TRIAL DEMANDED

*Defendant*

1. Plaintiff Mrs. Linda Smith brings this action against Defendant Xavier Becerra, in his official capacity as the Secretary of the United States Department of Health and Human Services, to obtain injunctive relief for violation of federal law. Plaintiff makes the following allegations based on the investigation of counsel and on information and on personal knowledge.

## **I. JURISDICTION**

2. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) and 1395ff. Mrs. Smith is filing suit after a final decision of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of her Medicare claim (and, therefore, has exhausted his administrative remedies), the amount-in-controversy is more than \$1,600 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision.

3. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) because this action is being brought in the District of Utah, where Mrs. Smith resides.

## **II. PARTIES**

4. Plaintiff Mrs. Linda Smith is an individual and a resident of the State of Utah. Mrs. Smith is eligible for Medicare on the basis of age and/or disability as previously determined by the Secretary.

5. Defendant Xavier Becerra is sued in his official capacity as the acting Secretary of the United States Department of Health and Human Services.

### **III. FACTUAL BACKGROUND**

6. Diabetes is a disease in which the body either does not produce any/enough insulin (Type I) or does not properly respond to/regulate blood glucose levels (Type II). As a result, the individual may experience high or low blood glucose levels for a prolonged period of time. High or low blood glucose levels for long periods lead to heart disease, stroke, kidney failure, ulcers (sometimes resulting in amputation), eye damage (sometimes resulting in blindness), and ultimately death. As of 2015, diabetes was the seventh leading cause of death in the United States.<sup>1</sup> Through 2012, the costs related to diabetes (healthcare and lost productivity) were estimated at \$245 billion annually.<sup>2</sup>

7. In addition to monitoring through blood tests (see below), many diabetics feel physical symptoms such as blurred vision, fatigue, hunger, and increased thirst that alert them their blood glucose levels are too high or too low. As a result, the diabetic is able to take corrective action (e.g., drinking orange juice).

8. However, the longer a patient lives with diabetes, the more they lose sensitivity to out of range glucose levels. Thus, they no longer have any physical

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<sup>1</sup> See Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 10.

<sup>2</sup> *Id.*

sense that their glucose level may be too high or too low to indicate that corrective action must be taken. This is referred to as “hyperglycemic or hypoglycemic unawareness.”

9. Further, the blood glucose levels of some diabetics are prone to wild and rapid swings either up or down. For example, in the span of minutes, glucose levels may drop precipitously low and the patient may fall into a diabetic coma that proves fatal. This is referred to as “brittle diabetes.”

10. It is estimated that one in 20 individuals with diabetes dies each year in their sleep due to an undetected fatal low blood sugar. This is known as “dead in bed syndrome.”<sup>3</sup>

11. For such individuals, to effectively monitor glucose levels, blood testing needs to be performed several times a day, even during the night.

#### **A. Glucose Tests**

12. Prior to the early 2000’s, the most common method for patients to monitor blood glucose levels was by pricking a finger to draw blood. Blood was then placed on a test strip coated with glucose oxidase. Glucose in the blood and the glucose oxidase on the test strip react and, in doing so, consume oxygen. The oxygen consumption: 1) results in an electrical charge that is measured by a glucose meter;

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<sup>3</sup> <https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome> (accessed October 9, 2018).

or 2) results in a color change on the test strip which is correlated with actual blood glucose levels.

13. This method has several disadvantages. First, it requires patients to prick their fingers multiple (*e.g.*, 12) times a day. Further, because some of those times will be when the patient is sleeping, the patient must awake throughout the night and cannot get a full night's sleep. Second, because it is done on relatively long intervals, brittle diabetes patients may suffer an episode between testing periods. Thus, a brittle diabetes patient fully compliant with this testing procedure may still die because the onset of symptoms is so quick.

#### **B. Continuous Glucose Monitors**

14. The disadvantages of finger prick/test strips led researchers to develop continuous glucose monitors which became available starting in the mid-2000s. When using a CGM, a disposable sensor is placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells. These interstitial fluids contain glucose that has come from the blood and is on the way to the cells. Thus, interstitial glucose is correlated with the glucose in blood itself. Current CGM sensors last for a week and measure glucose levels every five to seven minutes (*i.e.*, more than 200 times a day) without requiring patient interaction - including when the patient is sleeping.

15. The output from a CGM sensor is transmitted, via a transmitter, to a CGM receiver/monitor or even a smart phone/tablet. A CGM transmitter typically lasts for several months. The CGM receiver/monitor or smart phone/tablet may monitor the detected glucose levels and report the results to the patient or a healthcare provider and/or trigger an alert. Further, when using a smart phone or tablet, an application on the device can plot glucose trends and perform further analyses.

16. Typically, the CGM is calibrated by finger prick/test strip testing twice a day. Some newer CGM devices eliminate the need for calibration.

17. Accordingly, CGMs offer many advantages over finger prick/test strips. First, they monitor glucose levels much more frequently - meaning that brittle diabetes patients enjoy decreased risk of death from a rapid onset of symptoms. Second, even for non-brittle diabetes patients, the increased monitoring frequency leads to much finer glucose level control, thereby reducing diabetes related health complications. Third, the monitoring occurs without patient interaction - meaning that patients can sleep through the night and/or not interrupt their regular activities. Fourth, patients are not pricking themselves as frequently – meaning that they do not suffer from near continuous injuries and sources of infection and discomfort.

18. Fifth, the CGM provides trend information regarding how quickly glucose levels are dropping or rising. The trend information is used by patients for

the immediate short term management of their diabetes (*e.g.*, “Do I have time to make it to the lunch meeting or should I pull over now and drink juice?”), and are used by clinicians for the long term management of diabetes (*e.g.*, the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months).

19. Overall, these advantages lead to improved glucose monitoring, reduced costs, increased quality of life, and reduced risk of death or other complications.

20. Moreover, CGMs result in decreased health care costs and improved outcomes. Because complications related to glucose control are reduced/avoided, the overall expense of treating a diabetic patient is reduced. For example, many diabetic patients require ambulance transport to the hospital when they suffer an incident. In 2014, more than 450,000 emergency room visits were the result of hyperglycemic or hypoglycemic incidents among diabetics.<sup>4</sup> These episodes are very expensive and a CGM reduces their frequency. Of course, the ultimate cost is death and CGMs reduce the events that can lead to that result.

### **C. CGM Cost Coverage**

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<sup>4</sup> See Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 9.

21. Modern CGMs cost approximately \$300/month for purchase of the CGM receiver, transmitter, disposable sensors, and test strip supplies for result calibration.

22. The advantages of CGMs over finger pricks/test strips are widely recognized in the health care field. Indeed, CGMs have become the standard of care for treating brittle diabetes. As a result, ~98% of private health care providers cover CGM related costs.<sup>5</sup>

23. For many patients, doctors describe a CGM as “life-saving.”

24. Further, the FDA has approved one CGM device to completely replace finger pricks/test strips.<sup>6</sup>

25. Inexplicably, Medicare has resisted covering CGMs. Except with regard to one CGM system, Medicare deems CGMs “not primarily and customarily used to serve a medical purpose” and, therefore, not covered durable medical equipment (DME).

#### **D. Durable Medical Equipment**

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<sup>5</sup> See <https://provider.dexcom.com/reimbursement/commercial-reimbursement>

<sup>6</sup> See Food and Drug Administration, Premarket Approval P120005/S041 (December 20, 2016).

26. Medicare covers “durable medical equipment.” Pursuant to 42 U.S.C. § 1395x(n), “durable medical equipment” is not defined, except by example. One such example is “glucose monitors.”

27. The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is “durable medical equipment” within the meaning of § 1395x(n) (see 42 C.F.R. § 404.202). Equipment is considered “durable medical equipment” if it:

- a) Can withstand repeated use;
- b) Has an expected life of at least 3 years;
- c) Is primarily and customarily used to serve a medical purpose;
- d) Generally is not useful to an individual in the absence of illness or injury; and
- e) Is appropriate for use in the home.

**E. CMS-1682-R**

28. Pursuant to 42 U.S.C. § 1395hh(2):

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

29. The “paragraph (1)” referred to requires “notice and comment” as described in the remainder of 42 U.S.C. § 1395hh.

30. Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS “final opinion and order” with regard to CGM coverage.

31. By its own terms, that Ruling is “binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration ...”

32. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

33. As set forth there, if a CGM does not completely replace finger prick/test strips, CMS considers the device not “primarily and customarily used to serve a medical purpose.” This is so, CMS contends, because patients do not “mak[e] diabetes treatment decisions, such as changing one’s diet or insulin dosage based solely on the readings of the CGM[.]” See CMS-1682-R at 6-7. CMS calls these CGM’s “non-therapeutic.”

34. The Ruling determines that one CGM that has been FDA approved to completely replace finger pricks/test strips is DME (the Dexcom G5). See CMS-1682-R at 7-10. In particular, the Ruling determines that the receiver/monitor portion of a CGM lasts more than 3 years and, including other factors, that the whole system is DME within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

35. Both before and after issuance of CMS-1682-R, the Secretary has refused coverage of CGM devices made by Medtronic and Dexcom (other than the Dexcom G5) on the grounds that they are not “primarily and customarily used to serve a medical purpose.”

36. Further, as a result of CMS-1682-R, the discretion ALJ's previously had to award coverage (even in the face of an alleged LCD) was eliminated. As a result, it is futile to submit claims for non-Dexcom G5 devices with dates of service after January 12, 2017. Because the ALJs no longer have discretion, those claims must be denied.

37. Without notice and comment, CMS-1682-R was subsequently incorporated into LCD L33822 and Policy Article A52464, generally excluding CGMs.

38. Thus, the Ruling substituted the non-statutory/regulatory term "therapeutic" for the previous non-statutory/regulatory term "precautionary" as the criteria/basis for denials.

#### **F. Other Litigation Related to CGMs**

39. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. This is so, the Secretary contends, because CGMs are not "primarily and customarily used to serve a medical purpose."

40. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national or local coverage determination (NCD/LCD) excluding CGM coverage, a local coverage article (LCA) described CGMs as excluded as "precautionary." LCA A52464.

41. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

42. At the Medicare Administrative Law Judge ("ALJ") level, through 2017, more than 40 ALJs had considered the Secretary's position that a CGM is not "primarily and customarily used to serve a medical purpose" and rejected that claim more than 55 times. A listing of relevant ALJ decisions may be found at <http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf>.

43. As to the Secretary's base position that a CGM is not "primarily and customarily used to serve a medical purpose", that position has been rejected by five district courts.

44. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.); and *Zieroth v. Azar*, 2020 WL 5642614 (N.D. Cal. Sept. 22, 2020) (Chesney, J.); and *Olsen v. Cochran*, 2021 WL 711469 (E.D. Wa. February 23, 2021) (Mendoza, J.) the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" was unreasonable, erroneous, not supported by substantial evidence, and in each case, ordered the Secretary to provide CGM coverage.

45. In addition, all the courts (except *Olsen* where the fee motion is pending) found that the Secretary's position lacked "substantial justification" and awarded attorney's fees to the plaintiffs pursuant to the Equal Access to Justice Act. *See* 5 U.S.C. § 504; 28 U.S.C. § 2412.

46. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at \*18.

#### **IV. Facts Specific to Mrs. Smith**

47. Linda Smith is a 76-year old mother of five, grandmother to 19, wife of 55 years to husband Kent, and former high school English teacher. In her free time, Mrs. Smith enjoys volunteering with her church and spending time with her family. For many years, Mrs. Smith has trained medical professionals and parents in dealing with Attention-deficit, Hyperactivity disorders and founded several ongoing national programs in this area.

48. Mrs. Smith is a Type I "brittle" diabetic (*i.e.*, her glucose levels are prone to wild and rapid swings). In addition, Mrs. Smith suffers from hypo/hyperglycemic unawareness (*i.e.*, she has no physical sensations – head aches, sweats, etc. – that alert her that her glucose levels need to be adjusted).

49. Prior to receiving an insulin pump and a CGM, Mrs. Smith was found non-responsive and had to be revived multiple times and was involved in a car accident requiring hospitalization as a result of her uncontrolled diabetic condition.

50. Given her brittle diabetes and hypoglycemic unawareness, traditional finger stick checking was not sufficient to manage Mrs. Smith's diabetes such that she continued to suffer a risk of death and other complications.

51. To assist with management of her diabetes, Mrs. Smith was fitted with an insulin pump and prescribed the Medtronic MiniMed continuous glucose monitor.

52. The Medtronic MiniMed CGM communicates with Mrs. Smith's insulin pump to properly regulate the amount of insulin being dispensed.

53. Since receiving an insulin pump and the CGM which interfaces with it, Mrs. Smith has had no health incidents as a result of her diabetic condition.

#### **V. Mrs. Smith's Prior Litigation of CGM Coverage**

54. Mrs. Smith has previously litigated the issues of whether her CGM (and supplies) is "primarily and customarily used to serve a medical purpose", is "durable medical equipment", is "medically reasonable and necessary", and a Medicare covered benefit.

55. On October 29, 2015, Mrs. Smith received supplies for use with her Medtronic MiniMed 630G continuous glucose monitor.

56. Mrs. Smith's claim for Medicare coverage was denied initially, denied on redetermination, and denied on reconsideration.

57. Thereafter, through her counsel, Parrish Law Offices, Mrs. Smith requested an ALJ hearing and the matter was assigned to ALJ Lambert in ALJ Appeal No. 1-6020086584.

58. The Secretary had a full and fair opportunity to litigate before ALJ Lambert.

59. The issues of whether Mrs. Smith's CGM (and supplies) was "primarily and customarily used to serve a medical purpose", "durable medical equipment", "medically reasonable and necessary" and covered by Medicare was actually litigated before ALJ Lambert.

60. On May 1, 2017, ALJ Lambert issued a decision fully favorable to Mrs. Smith.

61. In particular, ALJ Lambert found that Mrs. Smith's CGM (and supplies) was "primarily and customarily used to serve a medical purpose", "durable medical equipment", "medically reasonable and necessary" and covered by Medicare.

62. ALJ Lambert's determination that Mrs. Smith's CGM (and supplies) was "primarily and customarily used to serve a medical purpose", "durable medical

equipment”, “medically reasonable and necessary” and covered by Medicare was a necessary component of ALJ Lambert’s decision finding coverage.

63. Thereafter, the Secretary (through CMS) filed exceptions to ALJ Lambert’s decision and, on August 29, 2017, the Medicare Appeals Council (MAC) reversed ALJ Lambert’s decision and remanded the case back to ALJ Lambert for further consideration.

64. On April 4, 2018, ALJ Lambert conducted another hearing where Mrs. Smith both appeared and was represented by her counsel, Debra Parrish of Parrish Law Offices.

65. The Secretary had a full and fair opportunity to litigate before ALJ Lambert.

66. The issues of whether Mrs. Smith’s CGM was “primarily and customarily used to serve a medical purpose”, “durable medical equipment”, “medically reasonable and necessary” and covered by Medicare was actually litigated before ALJ Lambert.

67. On April 24, 2018, ALJ Lambert issued a decision fully favorable to Mrs. Smith in ALJ Appeal No. 1-6020086584R1.

68. In particular, ALJ Lambert found that Mrs. Smith’s CGM (and supplies) was “primarily and customarily used to serve a medical purpose.”

69. ALJ Lambert also found that Mrs. Smith's CGM (and supplies) was "durable medical equipment."

70. ALJ Lambert also found that Mrs. Smith's CGM (and supplies) was "medically reasonable and necessary."

71. ALJ Lambert also found that Mrs. Smith's CGM (and supplies) was covered by Medicare.

72. ALJ Lambert's determinations that Mrs. Smith's CGM (and supplies) was "primarily and customarily used to serve a medical purpose", "durable medical equipment", and "medically reasonable and necessary" was a necessary component of ALJ Lambert's decision finding coverage by Medicare.

73. The Secretary had an opportunity to appeal ALJ Lambert's decision.

74. The Secretary did not appeal ALJ Lambert's decision.

75. ALJ Lambert's decision became final on or after June 25, 2018.

## **VI. The Claims at Issue in this Case**

### **ALJ Appeal No. 1-8048583213**

76. On May 15, 2018, Mrs. Smith received supplies related to her CGM including sensors.

77. Mrs. Smith's claim for coverage for these items was rejected on June 8, 2018, on the grounds that: "Medicare does not pay for this item or service." Thereafter, Mrs. Smith sought redetermination.

78. Mrs. Smith's request for redetermination was denied on July 10, 2018 on the grounds that Mrs. Smith's CGM was not "durable medical equipment" as defined in CMS 1682-R. Thereafter, Mrs. Smith sought reconsideration.

79. Mrs. Smith's request for reconsideration was denied on August 3, 2018. Again, Mrs. Smith's claim for coverage was denied on the grounds that her CGM was not "durable medical equipment" as defined in CMS 1682-R.

80. Though her counsel (Parrish Law Office), Mrs. Smith filed an appeal that was assigned to ALJ Mark Win.

81. On December 11, 2018, ALJ Win conducted a hearing at which Mrs. Smith and her counsel (Mr. James Pistorino).

82. The Secretary had a full and fair opportunity to litigate before ALJ Win.

83. On April 19, 2019, ALJ Win issued a decision in ALJ Appeal No. 1-8048583213 denying Medicare coverage of Mrs. Smith's CGM claim.

84. In particular, ALJ Win found that Mrs. Smiths' CGM (and supplies) were not "durable medical equipment" as defined in CMS 1682-R.

**ALJ Appeal No. 1-8048536100**

85. On November 16, 2017, Mrs. Smith received supplies related to her CGM.

86. Mrs. Smith's claim for coverage for these items was denied initially, denied on redetermination, and denied on reconsideration.

87. Thereafter, through her counsel (Parrish Law Office), Mrs. Smith requested an ALJ hearing that was assigned to ALJ Win.

88. On February 19, 2019, ALJ Win held a hearing at which Mrs. Smith and her counsel (James Pistorino) appeared.

89. On April 19, 2019, ALJ Win issued a decision in ALJ Appeal No. 1-8048536100 denying Medicare coverage of Mrs. Smith's CGM claim.

90. In particular, ALJ Win held that Mrs. Smith's CGM (and supplies) was not "durable medical equipment" as defined in CMS 1682-R and, therefore, was not a Medicare covered benefit.

91. Mrs. Smith timely appealed ALJ Win's decisions in both ALJ Appeal Nos. 1-8048583213 and 1-8048536100 to the Medicare Appeals Council.

**M-19-1973**

92. On February 26, 2021, the Council issued a single decision (M-19-1973) adopting ALJ Win's decisions in both ALJ Appeal Nos. 1-8048583213 and 1-8048536100.

93. The total cost of the claims at issue in M-19-1973 is \$2,838.

94. Accordingly, Mrs. Smith's CGM claims were rejected as not "durable medical equipment" because they are not "primarily and customarily used to serve

a medical purpose” either as defined in CMS 1682-R or on the grounds they are “precautionary.”

95. Because the Council concluded that Mrs. Smith’s CGM claims did not qualify as “durable medical equipment”, Mrs. Smith’s claims were necessarily excluded from coverage as not “medically reasonable and necessary.”

96. Thereafter, Mrs. Smith timely filed suit in this Court.

## **VII. CAUSES OF ACTION**

### **COUNT I**

#### **Violation of 5 U.S.C § 706(2)(A)**

(arbitrary and capricious, abuse of discretion, not in accordance with law)

97. Paragraphs 1-96 are incorporated by reference as if fully set forth herein.

98. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary’s Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

99. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary’s Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT II**

**Violation of 5 U.S.C § 706(2)(C)**

(in excess of statutory jurisdiction, authority, or  
limitations or short of statutory right)

100. Paragraphs 1-96 are incorporated by reference as if fully set forth herein.

101. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

102. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT III**

**Violation of 5 U.S.C § 706(2)(D)**

(without observance of procedure required by law)

103. Paragraphs 1-96 are incorporated by reference as if fully set forth herein.

104. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related

supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

105. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law (e.g., notice and comment required for modification of LCDs) and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT IV**  
**Violation of 5 U.S.C § 706(2)(E)**  
(not supported by substantial evidence)

106. Paragraphs 1-96 are incorporated by reference as if fully set forth herein.

107. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

108. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that a CGM and its related supplies covered durable medical equipment

and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

### **VIII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) finding that CGMs (whether they completely replace finger prick/test strips or not) are DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(3) directing the Secretary to provide coverage for the CGM claims at issue in this case; and

(4) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not DME is not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Such further and other relief this Court deems appropriate.

Dated: April 2, 2021

Respectfully submitted,

PARRISH LAW OFFICES

/s/ James C. Pistorino

James C. Pistorino

*Attorneys for Plaintiff*

LEAR & LEAR PLLC

/s/ Phillip Wm. Lear

Phillip Wm. Lear

Local Attorneys for Plaintiff